UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

SOPHIAS CURE INC. a/k/a SOPHIA'S CURE FOUNDATION, Plaintiff, - against - AVEXIS, INC., et al., Defendants.	:	**Civil Action No. 2:16-cv-00865-MHW-EPD** **Judge Michael H. Watson** **Magistrate Judge Elizabeth Preston Deavers**

DEFENDANTS AVEXIS, INC., SEAN NOLAN AND ARVIND SREEDHARAN'S MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT

Defendants AveXis, Inc. ("AveXis"), Sean Nolan and Arvind Sreedharan (collectively, the "AveXis Defendants") hereby move to dismiss Plaintiff Sophia's Cure Inc. a/k/a Sophia's Cure Foundation's ("SCF") First Amended Complaint pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure ("Rule 12(b)(6)") for failure to state a claim. The grounds supporting this motion to dismiss are more fully set forth in the attached memorandum in support.

DATED: December 19, 2016

Respectfully submitted,

/s/ Shawn J. Organ

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MEMORANDUM IN SUPPORT

I. PRELIMINARY STATEMENT

The First Amended Complaint ("Amended Complaint" or "Am. Compl.") fails to state a claim for tortious interference against the AveXis Defendants for several reasons. SCF is a non-profit charity formed to assist with funding research for the treatment of spinal muscular atrophy ("SMA") and to provide advocacy and support for families affected by the disease. As alleged in the Amended Complaint, SCF donated funds to support Nationwide Children's Hospital's gene therapy clinical work relating to SMA. SCF's newly-minted claim is that, by virtue of its donation, it is entitled to be identified to the Food and Drug Administration ("FDA") as the "sponsor" for any Investigational New Drug application or clinical trials associated with the gene therapy and to reap the monetary benefits resulting from any successful development of a treatment. Nothing in the Donation Agreement between SCF and the Nationwide Children's Hospital Foundation ("NCH Foundation") bestows any such rights on SCF. To make its claim, SCF distorts the plain meaning of one provision in the Donation Agreement—which specifies that SCF be given public recognition for its donation in support of early clinical work—to assert broad rights over any gene therapy that is developed, including the right to enormous monetary damages.

SCF's claim is wholly unsupported by its agreement with the NCH Foundation. Nothing in the Donation Agreement gave SCF the right to be designated the "sponsor" with respect to regulatory filings or orphan drug designation, nor did the Donation Agreement confer (or even reference) any marketing or commercialization rights. The one-page Donation Agreement is simple: SCF agreed to donate funds to support certain early clinical work, the NCH Foundation agreed to make a matching donation, and the NCH Foundation agreed that in any publications it issued about the specified clinical work, it would recognize SCF as the

"primary sponsor" of the project. SCF's invented "right" to be named as the "sponsor" of the therapy in regulatory filings is nowhere to be found in the Donation Agreement; accordingly, the NCH Foundation's "failure" to name SCF as the "sponsor" for those purposes was not a breach of the Donation Agreement. Absent any breach of the agreement by the NCH Foundation, SCF cannot plead tortious interference by any of the AveXis Defendants.

In any event, even if SCF had plausibly alleged a breach of the Donation Agreement, the Amended Complaint lacks any factual allegations establishing that the AveXis Defendants had specific knowledge of the terms of the Donation Agreement, much less that they intentionally and improperly caused the NCH Foundation to "breach" it. AveXis's involvement in this matter stems from its entry into a license agreement with Nationwide Children's Hospital ("NCH") with respect to certain patents for the therapy and treatment of SMA. SCF does not allege that when AveXis entered into that license agreement, the AveXis Defendants had any reason to believe SCF, as a donor that had supported NCH's early clinical work, had any rights with respect to regulatory filings for the gene therapy. Nor does the Amended Complaint plead any facts suggesting that the AveXis Defendants had knowledge of any purported breach of an agreement by the NCH Foundation or any of the other NCH Entities. Further, even if the Donation Agreement did provide the sponsorship right that SCF asserts (which it does not), no fact pleaded in the Amended Complaint plausibly suggests that the AveXis Defendants deliberately interfered with the NCH Foundation's performance of the Donation Agreement. Moreover, other than conclusory assertions, no factual allegations in the Amended Complaint establish that the AveXis Defendants acted unjustifiably and with an improper motive. To the contrary, the only plausible inference that can be drawn from the factual allegations in the Amended Complaint is

that AveXis entered into a license agreement with NCH in good faith and exercised its contractual right to become sponsor of the IND application pursuant to that license agreement.

In short, the Amended Complaint fails to satisfy the elements of tortious interference, and the claim against the AveXis Defendants should be dismissed.

II. FACTUAL BACKGROUND[1]

A. The Parties

The AveXis Defendants: AveXis is a gene therapy company "passionately committed to moving gene therapies into the clinical settings for patients and families devastated by rare and orphan neurological genetic diseases." (¶ 30.)[2] AveXis's proprietary gene therapy product, AVXS-101, is currently in development for the treatment of SMA. (*See* ¶¶ 1, 66, 83.) Defendant Sean Nolan is AveXis's President and CEO, positions he has held since June 2015. (¶ 18.) Defendant Arvind Sreedharan is AveXis's Vice President of Business Operations, a position he has held since August 2015. (¶ 19.)

Defendant John Carbona: Defendant John Carbona was AveXis's CEO until he resigned from that position in May 2015. (*See* ¶¶ 9, 17.)

The NCH Defendants: NCH, the NCH Foundation, and the Research Institute at Nationwide Children's Hospital ("Research Institute") (collectively, "NCH Entities") are Ohio non-profit organizations. (¶¶ 13-15.) The Research Institute and NCH Foundation are subsidiaries of Nationwide Children's Hospital. (¶¶ 14-15.) The Research Institute provides "basic, clinical, translational, and health services research at NCH." (¶ 15.) The NCH Foundation "builds philanthropic partnerships with individuals, corporations, and organizations to advance NCH's programs of patient care, advocacy, research, education and service." (¶ 14.)

[1] The following facts are derived from the Amended Complaint and are accepted as true only for purposes of this Motion.

[2] All citations to "¶ _" refer to the numbered paragraphs in the Amended Complaint.

Defendant Brian Kaspar: Dr. Brian Kaspar is employed by the NCH Entities and on the faculty of the NCH Research Institute. (¶¶ 16, 29.) He is also currently Chief Scientific Officer at AveXis and a member of the AveXis Board of Directors.[3] (¶¶ 16, 29, 69.) Dr. Kaspar and the NCH Entities have been working for years to develop treatments for SMA. (¶¶ 1, 3, 32-34.)

Plaintiff Sophia's Cure Foundation: Sophia's Cure Inc. a/k/a Sophia's Cure Foundation is a non-profit founded in June 2009 by Vincent and Catherine Gaynor, parents of Sophia Gaynor, who is afflicted with SMA. (¶¶ 2, 23.) SCF's mission is "to assist in funding for clinical research towards finding a cure for [SMA]." (¶ 26.) SCF provides support and advocacy for families affected by SMA. (*Id.*)

B. The Amended Complaint's Allegations

1. scAAV9 Gene Therapy

SMA is a genetic disease that affects the nervous system that controls voluntary muscle movement. (¶ 24.) It leads to the inability to perform the basic functions of life and has no cure or proven treatments. (¶ 25.) In the hopes of finding a cure for SMA, the NCH Entities have been working on a gene therapy for SMA for several years. (*See* ¶¶ 1, 3.)

2. SCF's 2012 Donation Agreement with NCH

In October 2012, SCF donated funds to the NCH Foundation "for the funding of clinical work associated with the Phase 1 Vascular Gene Transfer of the Survival Motor Neuron Gene by scAAV9 for SMA Type 1 patients." (¶¶ 40-42; Am. Compl. Ex. 2.) Specifically, on October 15, 2012, SCF and the NCH Foundation executed a one page Donation Agreement (the "Donation Agreement," attached to the Amended Complaint as Exhibit 2), providing that SCF would

[3] The Amended Complaint alleges that Dr. Kaspar has been continuously affiliated with the Research Institute since 2010, and that he assumed his roles with AveXis in October 2012. (*See* ¶¶ 29, 69.)

donate $550,000 toward Phase 1 of the scAAV9 clinical work and that the NCH Foundation would match that donation. (¶ 40; Am. Compl., Ex. 2.) The Donation Agreement also provided that the NCH Foundation would recognize SCF as "primary sponsor" in "all publications issued by" the NCH Foundation referencing the scAAV9 clinical work. (¶ 43, Am. Compl. Ex. 2.)

3. The IND Application, Orphan Drug Designation and AveXis's IND Option

The NCH Research Institute submitted an Investigational New Drug ("IND") application[4] to the FDA for scAAV9 in 2013. (¶ 58.) In September 2013, the FDA approved the IND application. (¶ 62.)

The following month, in October 2013, NCH entered into a license agreement with AveXis. Pursuant to the license agreement, NCH granted AveXis an exclusive license "to certain patents held by NCH for the therapy and treatment of SMA." (¶ 66.) AveXis was also given "the right to become sponsor of the IND after completion of the Phase 1 clinical trial" (the "IND option"). (*Id*.)

By October 3, 2014, the FDA designated scAAV9 an orphan drug.[5] (¶ 83.) A year later, on October 14, 2015, AveXis exercised its IND option and became sponsor of the IND. (¶ 106.) The FDA approved AveXis as the sponsor of the IND on November 6, 2015. (¶ 107.)

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[4] An IND application "is a request for [FDA] authorization to administer an investigational drug to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug that is not the subject of an approved new drug application." *Information for Sponsor-Investigators Submitting Investigational New Drug Applications (INDs)*, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm071098.htm#form1571 (last updated August 31, 2015). (The Court may take judicial notice of matters of public record, including information on the FDA's website. *See, e.g.*, *Reeves v. PharmaJet, Inc.*, 846 F. Supp. 2d 791, 794 n.1 (N.D. Ohio 2012) (taking judicial notice of FDA records on the agency's website).) Under the applicable regulations, the sponsor of an IND application is defined as the "person ***who takes responsibility for and initiates a clinical investigation***." 21 C.F.R. § 312.3 (emphasis added).

III. LEGAL STANDARD

Under Rule 12(b)(6), a court must dismiss a complaint if it fails to state a claim upon which relief can be granted. As the Supreme Court has emphasized, "labels and conclusions, and a formulaic recitation of the elements of a cause of action will not" survive a motion to dismiss. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Instead,

> a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.

Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (citation omitted). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.*; *Perkins v. Wells Fargo Bank, N.A.*, No. 2:11-cv-952, 2012 WL 5077712, at *4 (S.D. Ohio Oct. 18, 2012) ("[A] court need not accept as true a legal conclusion couched as a factual allegation.") (internal quotations omitted). Thus, unless a plaintiff can state "enough facts" to "nudge[] [its] claims across the line from conceivable to plausible, the[] complaint must be dismissed." *Twombly*, 550 U.S. at 570.

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[5] The Orphan Drug Act ("ODA") grants "special status to a drug or biological product ("drug") to treat a rare disease or condition upon request of a sponsor." It "qualifies the sponsor of the drug for various development incentives of the ODA, including tax credits for qualified clinical testing." *Designating an Orphan Product: Drugs and Biological Products*, http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/HowtoapplyforOrphanProductDesignation/default.htm (last updated May 2, 2016). One of the development incentives of orphan drug status is an exclusive marketing right for seven years from the date of approval from the FDA. *See* 21 U.S.C. § 360cc(a); *see also* 21 C.F.R. §§ 316.31 and 316.34. Under the applicable regulations, sponsor "means the entity that assumes responsibility for a clinical or nonclinical investigation of a drug, including the responsibility for compliance with applicable provisions of the act and regulations." 21 C.F.R. § 316.3(b)(15).

IV. THE AMENDED COMPLAINT FAILS TO STATE A CLAIM FOR TORTIOUS INTERFERENCE[6]

To state a claim for tortious interference, a plaintiff must allege facts that establish the following elements: (1) the existence of a contract, (2) the wrongdoer's knowledge of the contract, (3) the wrongdoer's intentional procurement of the contract's breach, (4) the lack of justification; and (5) resulting damages. *The William Powell Co. v. Nat'l Indem. Co.*, 141 F. Supp. 3d 773, 784 (S.D. Ohio 2015) (citing *Fred Siegel Co., L.P.A. v. Arter & Hadden*, 707 N.E.2d 853, 858 (Ohio 1999)).[7]

Plaintiff fails to state a plausible claim for tortious interference for multiple reasons. First, Plaintiff fails to plead facts establishing that any contract has been breached. Moreover, even assuming that the Amended Complaint sufficiently alleges that the NCH Foundation breached the Donation Agreement, the Amended Complaint is devoid of any well-pleaded factual allegations that the AveXis Defendants (a) had knowledge of the terms of the Donation Agreement, (b) intentionally interfered with Plaintiff's purported rights under this agreement, or (c) lacked justification in entering into a license agreement with NCH. Plaintiff's tortious interference claim should therefore be dismissed.

A. SCF's Failure to Adequately Plead Any Breach of Contract Defeats its Tortious Interference Claim

It is fundamental that a contract must have been breached in order for a tortious interference claim to be viable. *Bunn Enterprises, Inc. v. Ohio Operating Engineers Fringe*

[6] The NCH Defendants are moving separately to dismiss the Complaint. The AveXis Defendants adopt and incorporate by reference all arguments set forth in the NCH Defendants' Memorandum in Support to the extent they are applicable.

[7] This memorandum applies Ohio law. The same arguments would apply under New York law (where SCF is based) because the elements of a tortious interference claim are substantially the same in both states. *See AT&T Corp. v. Overdrive, Inc.*, No. 1:05CV1904, 2007 WL 120654, at *12-14 (N.D. Ohio Jan. 10, 2007) (reviewing the elements of tortious interference under New York and Ohio law).

Benefit Programs, 7 F. Supp. 3d 752, 759 (S.D. Ohio 2014) ("It is axiomatic that, if there is no breach, there can be no tortious interference.") , *aff'd*, 606 F. App'x 798 (6th Cir. 2015); *Dabrowski v. City of Twinsburg*, No. 5:14CV569, 2014 WL 5824786, at *2 (S.D. Ohio Nov. 10, 2014) (plaintiffs could not satisfy all of the required elements of tortious interference because lease agreement was not breached). Plaintiff alleges that the NCH Entities breached the October 15, 2012 Donation Agreement by failing to name SCF as the sponsor.[8] (*E.g.*, ¶¶ 5, 6, 51, 63, 67-69, 99.) By its plain terms, the Donation Agreement provides that Plaintiff bestowed a donation—a *gift*—upon the NCH Foundation. The Donation Agreement is exactly what it purports to be: a *donation* agreement; its "purpose" was "to outline a donation pledge and matching donation by and between" SCF and the NCH Foundation. The Donation Agreement provides that SCF "agrees to *gift* to" the NCH Foundation $550,000 "*for the funding of clinical work* associated with the Phase 1 Vascular Gene Transfer of the Survival Motor Neuron Gene by scAAV9 for SMA Type 1 patients (hereinafter, 'PROJECT')." (Am. Compl., Ex. 2 (emphasis added).) In consideration of Plaintiff's donation, the NCH Foundation agreed to match SCF's gift, resulting in total funding of $1,100,000 towards the Phase 1 clinical work. (*Id.*)

To concoct a breach of contract claim, Plaintiff seizes on one provision, under the subtitle, "PUBLIC RECOGNITION OF DONOR'S ROLE," that provides: "In all publications issued by [the NCH Foundation] that reference the PROJECT, [SCF] shall be recognized by name – The Sophia's Cure Foundation – as the primary sponsor of the PROJECT." (*Id.*) Nothing about this provision makes SCF the "sponsor" of the gene therapy, scAAV9.[9]

[8] The NCH Foundation is a party to the Donation Agreement; NCH and the Research Institute are not.

[9] SCF's right to public recognition applies only to the funding of the clinical work associated with the Phase 1 trial (the "Project"). It does not extend beyond the Phase 1 trial to all activities involving scAAV9.

Similarly, nothing about this provision brings SCF within the FDA's definition of the term "sponsor" for purposes of IND applications or clinical trials. *See* 21 C.F.R. § 312.3 (defining "sponsor" as "a person who takes responsibility for and initiates a clinical investigation"); *see also How to Read a Study Record – ClinicalTrials.gov*, https://clinicaltrials.gov/ct2/help/how-read-study ("The sponsor is the organization or person . . . who oversees the clinical study and is responsible for analyzing the study data.").

To the contrary, the provision only gives SCF the right to certain public recognition for its donation. In particular, SCF is entitled to receive public recognition only in connection with "publications" that are "issued by" the NCH Foundation.

The IND application, a regulatory submission to the FDA to obtain authorization to administer the investigational therapy to humans, was not a "publication." (Merriam-Webster defines "publication" as "a book, magazine, etc., that has been printed and made available to the public." *See* http://www.merriam-webster.com/dictionary/publication.) In fact, under FDA regulations, an IND application is strictly confidential and its existence is prohibited from being disclosed by the FDA unless already publicly disclosed or acknowledged. 21 C.F.R. § 312.130(a); *see also Sokolow v. FDA*, No. 1:97-CV-252, 1998 U.S. Dist. LEXIS 23672, at *9-10 (E.D. Tex. Feb. 19, 1998) (IND application "is the paradigmatic example of trade secret and confidential commercial information"). Moreover, as alleged in the Amended Complaint, the IND application was not even submitted by the NCH Foundation. (¶ 51.) For these two simple reasons alone, the submission of the IND application did not breach the Donation Agreement. SCF's attempt to expand the public recognition provision in the Donation Agreement so that it determines the content of subsequent filings with the FDA—in conflict with the applicable

definitions set forth in the federal regulations—is not supported by anything in the Donation Agreement itself.

Nor does anything in the Donation Agreement give SCF the right to monetary compensation from any commercialization of scAAV9.[10] Plaintiff alleges that SCF has the exclusive right to market scAAV9 for seven years. (¶ 45.) Tellingly, this purported "right" is nowhere to be found in the Donation Agreement. Instead, Plaintiff seemingly relies on a misinterpretation of the Orphan Drug Act. The Orphan Drug Act grants exclusive marketing rights to the sponsor of an approved orphan drug. *See* 21 U.S.C. § 360cc(a), 21 C.F.R. §§ 316.31 and 316.34. The "sponsor," as defined by the applicable regulations, is "the entity that assumes responsibility for a clinical or nonclinical investigation of a drug, including the responsibility for compliance with applicable provisions of the act and regulations." 21 C.F.R. § 316.3(b)(15). SCF is clearly not the entity that "assume[d] responsibility" for the scAAV9 clinical investigation, nor does it have any responsibility for compliance with the Orphan Drug Act or its regulations by virtue of donating funds toward the scAAV9 Phase 1 clinical work.[11] The public recognition provision of the Donation Agreement does not come close to suggesting that SCF assumed (or even contemplated assuming) responsibility for the clinical work toward which it donated funds.

In sum, Plaintiff's allegation that the NCH Foundation breached the Donation Agreement by failing to name SCF as the "sponsor" of the IND or clinical trials finds no support in the

[10] To the contrary, the 2011 Grant Agreement executed between SCF and the Research Institute provides that the Research Institute retained all ownership rights in any inventions or ideas developed as part of the project. (Am. Compl., Ex. 1 at 3.)

[11] The regulation also states that "[a] sponsor may be an individual, partnership, corporation, or Government agency and may be a *manufacturer, scientific institution, or an investigator regularly and lawfully engaged in the investigation of drugs*." 21 C.F.R. § 316.3(b)(15) (emphasis added). SCF does not meet any of these criteria.

actual terms of the Donation Agreement. The IND application was not a publication nor was it issued by the NCH Foundation. As defined in the Code of Federal Regulations, for purposes of an IND, "sponsor" means the entity that is responsible for and initiates the clinical study. The Donation Agreement does not make SCF responsible for the clinical study, nor does SCF allege otherwise. The Donation Agreement does not make SCF entitled to be the "sponsor" for the FDA's purposes; accordingly, the NCH Entities' "failure" to identify SCF as the sponsor did not breach the Donation Agreement.

B. Even if the Donation Agreement Were Breached, SCF Fails to Sufficiently Allege That the AveXis Defendants Had Any Knowledge of the Breach or Intentionally Procured Such Breach

Even if SCF has adequately alleged that the NCH Foundation breached the Donation Agreement by failing to name SCF as sponsor, SCF fails to sufficiently allege that AveXis knew about that breach, much less that AveXis intentionally procured it. To state a claim for tortious interference, a plaintiff must allege that the procurement of the breach was intentional and improper. *The William Powell Co.*, 141 F. Supp. 3d at 784; *Kenty v. Transamerica Premium Ins. Co.*, 650 N.E.2d 863, 866 (Ohio 1995). At the most elementary level, a claim for tortious interference with contract is made out where a defendant, through "coercive conduct," "threats," or "persuasion," induces some third party to breach its contract with the plaintiff. Dan B. Dobbs, Paul T. Hayden and Ellen M. Bublick, The Law of Torts § 632-33 (2016). SCF's allegations do not satisfy the most basic requirements of this tort; "the defendant must actually know of the contract's existence . . . *and must be aware . . . that his acts will interfere with it.*" *Id.* at § 621 (emphasis added).

First, accepting the allegations in the Amended Complaint as true, Plaintiff fails to allege that AveXis had specific knowledge of any of the terms of the Donation Agreement, much less the public recognition provision. Instead, SCF alleges that Dr. Kaspar, along with other

individuals employed by various NCH Entities, received a draft of the Donation Agreement in September 2012. (¶ 47.) SCF then asserts the legal conclusion that "[a]s a result, AveXis also received a copy of the Donation Agreement and became aware of the Donation and its terms." (¶¶ 49, 70.)

SCF's attempt to bridge the gap in its factual allegations by asserting that Dr. Kaspar's knowledge is imputed to AveXis as a matter of law is meritless. Knowledge obtained by a corporate director is imputed to the corporation only when the "information is obtained in the course and scope of employment and is related to a matter over which the director's authority extends." *Am. Mut. Share Ins. Corp. v. CUMIS Ins. Soc'y, Inc.*, No. 08AP-576, 2009 WL 205373, at *4 (Ohio Ct. App. Jan. 29, 2009); 3 William Meade Fletcher, *Fletcher Cyclopedia of the Law of Corporations* § 793 (2016) ("As a general rule, knowledge acquired or possessed by an officer or agent of a corporation otherwise than in the course of employment, or in relation to a matter not within the scope of his or her authority, is not notice to the corporation."). The Amended Complaint is devoid of any factual allegations showing that Dr. Kaspar received a copy of the Donation Agreement in his capacity as an AveXis officer, or that he sent or discussed the agreement with anyone at AveXis. Rather, SCF only alleges that Dr. Kaspar was copied on an email from an individual at the NCH Foundation to Mr. Gaynor and another NCH officer in September 2012 and then later included on an email from Mr. Gaynor in October 2012 regarding—but not attaching—the Donation Agreement. (*See* ¶¶ 47-53.) Other than SCF's inferential leap of law, nothing in the Amended Complaint establishes that AveXis had knowledge of the terms of the Donation Agreement. *Perkins*, 2012 WL 5077712, at *4 ("[A] court need not accept as true a legal conclusion couched as a factual allegation.") (internal quotations omitted).

The factual allegations in the Amended Complaint show that AveXis was not aware of the specific terms of the Donation Agreement at the time of the alleged breach, and demonstrate the hollowness of SCF's attempted reliance on imputed knowledge. Plaintiff alleges that the initial breach of the Donation Agreement occurred in September 2013 when the Research Institute submitted the IND application to the FDA without naming SCF as sponsor. (¶¶ 5, 58.) AveXis did not enter into the license agreement with NCH until a month later, in October 2013 (¶ 66), and did not exercise its right to be sponsor of the IND until two years later, in October 2015. (¶ 106.) SCF also alleges that NCH breached the Donation Agreement in April 2014 by submitting a registered clinical trial that listed Dr. Jerry Mendell as sponsor and SCF as a collaborator. (¶ 78.)

Tellingly, SCF alleges that John Carbona, at the time Chief Executive Officer of AveXis, asked Mr. Gaynor to provide AveXis with a copy of the Donation Agreement in July 2014, almost one year after the initial purported breach in September 2013, and expressed his concerns about potential written provisions he was only "vaguely familiar with," including the public recognition provision. (¶ 79.) Although the Amended Complaint alleges that "Carbona's July 30 email confirms AveXis's and Carbona's knowledge of the existence of the Donation Agreement and its terms" (¶ 81), the Amended Complaint does not allege that SCF provided a copy of the Donation Agreement or any other information that would have provided AveXis with knowledge of the specific terms that SCF now alleges had been breached.

Moreover, even if AveXis had knowledge of the Donation Agreement, nothing in the Amended Complaint alleges that the AveXis Defendants shared the strained reading of the public recognition clause that SCF now espouses. Without such evidence, SCF cannot meet its burden of establishing that AveXis deliberately caused the NCH Foundation to breach its

agreement with SCF. *See Crown Equip. Corp. v. Toyota Material Handling, Inc.*, 202 F. App'x 108, 111 (6th Cir. 2006) (for an alleged tortfeasor "[t]o be subject to liability . . ., the actor must have knowledge of the contract with which he is interfering *and of the fact that he is interfering with the performance of the contract.*") (emphasis added) (quoting Restatement (Second) of Torts § 766, cmt. i (1979)); *Tilahun v. Philip Morris Tobacco Co.*, No. C2 04 1078, 2005 WL 2850098, at *4 (S.D. Ohio Oct. 28, 2005) ("[T]o make out a claim for tortious interference with contract," a plaintiff must allege that the defendant "knew that the actions it requested of [the party in contract with plaintiff] would result in breach."). *Cf. Koyo Corp. of U.S.A. v. Comerica Bank*, No. 1:10 CV 2557, 2011 WL 4540957, at *9 (N.D. Ohio Sept. 29, 2011) (plaintiff alleged that it "apprised" defendant of its contract with a third party, and that the defendant's actions would thwart the third party's performance).

The Amended Complaint fails to plead sufficient facts to satisfy this element. Even if AveXis had knowledge (actual or imputed) of the specific terms of the Donation Agreement at the time of the alleged breach—which, as explained above, is not consistent with the facts alleged in the Amended Complaint—nothing indicates that AveXis believed that Plaintiff had any rights with respect to being named sponsor in the IND application or that SCF somehow had "an exclusive right to market scAAV9 for seven years" as a result of the gene therapy's orphan drug designation. (*See* ¶¶ 44-46, 90.) In other words, even if one or more of the NCH Entities breached an agreement with Plaintiff, no facts alleged in the Amended Complaint establish that AveXis was aware of that purported breach at the time it occurred.

Plaintiff alleges that in October 2015, long after the NCH Entities purportedly breached the Donation Agreement and two years after AveXis entered into a license agreement with NCH, its representative met with the AveXis Defendants and told them that its contract with the NCH

Foundation provided that "anytime there is a release of information, Sophia's Cure would be recognized as the Primary Sponsor." (¶ 101.) Accepting these allegations for purposes of this motion to dismiss, this conversation does not satisfy Plaintiff's burden; those statements do not establish that AveXis believed SCF was entitled to have been designated as the "sponsor" of the IND or that SCF owned legal rights to market scAAV9, rather than that SCF was entitled to public recognition for its support of the early research. Moreover, by that time, the NCH Foundation's alleged breach was more than two years old; nothing that the AveXis Defendants did following that conversation could have plausibly induced the prior breach. *See Crown Equip.*, 202 F. App'x at 113 ("evidence that a defendant learned material facts after the breach occurred is not probative of the defendant's knowledge or state of mind at the time of the breach").

Finally, the Amended Complaint contains no allegations that the AveXis Defendants procured any purported breach. A plaintiff establishes "intentional procurement" of breach by alleging that the "defendant acted with the purpose or desire to interfere with the performance of the contract" or "knew that interference was certain or substantially certain to occur as a result of its actions." *RFC Capital Corp. v. EarthLink, Inc.*, No. 03AP-735, 2004 WL 2980402, at *17 (Ohio Ct. App. Dec. 23, 2004); *Crown Equip. Corp. v. Toyota Material Handling, Inc.*, No. 3:04 CV 7051, 2005 WL 2849161, at *3 (N.D. Ohio Oct. 28, 2005), *aff'd*, 202 Fed. App'x 108 (6th Cir. 2006). The Amended Complaint alleges simply that AveXis entered into a license agreement and obtained certain rights from NCH; nothing in the Amended Complaint indicates that if AveXis had not been willing to enter the license agreement, NCH or any of the other NCH Entities would have named SCF as the sponsor in the IND application.

C. Plaintiff Fails to Allege That AveXis's Actions Were Unjustified

Even assuming that Plaintiff sufficiently alleged that AveXis somehow induced NCH's alleged breach of the Donation Agreement, there are no allegations to support any inference that such inducement was "unjustified." Under Ohio law, Plaintiff bears the burden of proving that the AveXis Defendants' actions were not justified. *See Super Sulky, Inc. v. U.S. Trotting Ass'n*, 174 F.3d 733, 742 (6th Cir. 1999). A defendant's interference is unjustified only if it was improper. *Wylie & Sons Landscaping LLC v. FedEx Ground Package Sys., Inc.*, No. 3:15 CV 706, 2016 WL 4440230, at *3 (N.D. Ohio Aug. 23, 2016) (noting that "improper interference includes conduct such as physical violence, fraudulent misrepresentations, illegal conduct, threats of criminal and civil lawsuits, and economic pressure."); *Contemporary Villages, Inc. v. Hedge*, No. 2:05-CV-170, 2005 WL 1229741, at *2 (S.D. Ohio May 24, 2005) (citing *Fred Siegel Co.*, 707 N.E.2d at 858).[12] For example, in *M.J. McPherson Servs., L.L.P. v. Sports Images, Inc.*, the court dismissed a tortious interference with business relationships claim where the complaint generally alleged "misconduct" but failed to "set forth facts demonstrating Defendant acted improperly." No. 5:06 CV 465, 2006 WL 2505925, at *4 (N.D. Ohio Aug. 28, 2006). In that case, the complaint alleged that defendant stole certain of plaintiff's client accounts, but it failed to explain the nature of the relationship between the defendant and these

[12] Under Ohio law, courts consider seven factors set forth in the Restatement (Second) of Torts § 767 to determine whether plaintiffs have satisfied the "improper" element: "(1) the nature of the actor's conduct, (2) the actor's motive, (3) the interests of the party with whom the actor has interfered, (4) the interests sought to be advanced by the actor, (5) the social interests of protecting the freedom of contracting and the interference with such, (6) the proximity or remoteness of the actor's conduct to the interference, and (7) the relations between the parties." *Wylie & Sons Landscaping LLC*, 2016 WL 4440230, at *3.

clients, or any facts supporting the conclusion that defendant's interference with plaintiffs' accounts was unjustified.[13]

Here, Plaintiff appears to allege that AveXis took two actions that "tortiously interfered" with SCF's rights under the Donation Agreement: (1) entering into a license agreement with NCH in 2013, and (2) exercising its right to be sponsor of the IND in October 2015, pursuant to the license agreement. (¶¶ 66, 106.) No factual allegations in the Amended Complaint come close to alleging improper conduct or a bad faith motive, and Plaintiff's barebones allegation that the AveXis Defendants "unjustifiably" interfered with the Donation Agreement is insufficient. (¶ 106.) *See M.J. McPherson*, 2006 WL 2505925, at *4 (general allegation of "misconduct" not sufficient). In fact, the allegations in the Amended Complaint simply underscore that AveXis entered into a license agreement (including the right to be the IND sponsor) in good faith and in the ordinary course of business. Because Plaintiff fails to allege that AveXis's conduct was carried out in bad faith or with the purpose of usurping Plaintiff's purported rights under the Donation Agreement, its tortious interference claim fails.

V. CONCLUSION

For the foregoing reasons, the Amended Complaint should be dismissed as to AveXis, Inc., Sean Nolan, and Arvind Sreedharan.

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[13] In contrast, in *Miami Valley Mobile Health Servs. Inc v. ExamOne Worldwide*, the court denied a motion to dismiss a tortious interference claim where the defendant company moved into the plaintiff company's territory and stole its clients, despite a contract between defendant and plaintiff stating that the area belonged to plaintiff. 852 F. Supp. 2d 925, 942 (S.D. Ohio 2012). From the existence of this contract, the court noted that it could then be "inferred that [d]efendant acted improperly . . . when it allegedly stole [p]laintiffs' clients." *Id.* at 943. Similarly, in *Koyo Corp.*, the court found that there was a "reasonable inference" from the complaint that defendant's conduct was "improper." 2011 WL 4540957, at *9. In that case, Plaintiff alleged that the defendant engaged in knowing and deceitful conduct, and loaned money to another company to maintain appearances that the company was operational, so that the company could collect payments (including the funds to which plaintiff claimed entitlement), and funnel them to defendant. *Id.*

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on December 19, 2016, the foregoing was electronically filed with the Clerk of the Court using the CM/ECF system, which will send a notification to the attorneys of record in this matter who are registered with the Court's CM/ECF system.

DATED: December 19, 2016

/s/ Shawn J. Organ

One of the Attorneys for Defendants AveXis, Inc., Sean Nolan and Arvind Sreedharan